

a lock for irreversibly locking the safety shield in its normally biased position covering the injection part, the lock being activated by sliding the shield from its normally biased position to a position exposing the injection part during an injection; and  
a visual indicator indicating that the safety shield is locked in the normally biased position.

2.  
19. The double pointed injection needle assembly according to claim 18, wherein the needle hub is provided with at least one indicating area and the safety shield is provided with at least one transparent area through which the indicating area(s) is visible when the safety shield has been irreversible locked in the normally biased position, thereby providing the user with a visual indication when the disposable double pointed injection needle is in a potentially safe position.

3.  
20. The double point injection needle assembly according to claim 19, wherein the hub further is provided with at least one additional indicating area that is visible through the transparent area(s) when the injection part of the needle has not been used.

B1  
4.  
21. The double pointed injection needle assembly according to claim 18, wherein the safety shield is provided with at least one indicating area and that the needle hub is provided with at least one transparent area through which the indicating area(s) is visible when said safety shield has been irreversible locked over the injection part of the needle, thereby providing the user with a visual indication when said disposable double pointed injection needle is in a potentially safe position.

5.  
22. The double pointed injection needle assembly according to claim 21, wherein the safety shield further is provided with at least one additional indicating area that is visible through the transparent areas when the needle has not been used to perform an injection.

6.  
23. The double pointed injection needle assembly according to claim 20, wherein the indicating areas and the additional indicating areas are provided with different colors.

24. The double pointed injection needle assembly according to claim <sup>3</sup>20 wherein the indicating areas and the additional indicating areas are provided with different symbols.

25. A safety injection needle assembly comprising:  
an elongated cannula having a distal end for injecting a patient;  
a hub in which the cannula is mounted;  
a moveable safety shield that moves relative to the cannula between a first position exposing the distal end and a second position covering the distal end; the safety shield being biased toward the second position;  
a locking means for irreversibly locking the safety shield in the second position after the shield is initially moved from the second position to the first position and then returned to the second position; and  
a visual indicator that shows when the shield is irreversibly locked in the second position, thereby preventing re-use of the needle assembly to administer a second injection after it has been already used to administer a first injection.

26. The safety needle assembly of claim <sup>8</sup>25, wherein the visual indicator shows a colored surface after the shield is irreversibly locked.

27. The safety needle assembly of claim <sup>8</sup>25, wherein the visual indicator shows a textured surface after the shield is irreversibly locked.

28. The safety needle assembly of claim <sup>8</sup>25, wherein the visual indicator shows a shaded surface after the shield is irreversibly locked.

29. A disposable double pointed injection needle comprising an elongated cannula having two sharp ends and an outside diameter,  
said needle cannula being fastened in a needle hub having a distal end and a proximal end, said proximal end being provided with a fastening mechanism for mounting said needle hub on to a syringe having a cartridge,  
said needle cannula having an injection part and a cartridge part, the cartridge part for inserting into a cartridge that is covered by said needle hub, the injection part for entering into a human body during injection, the injection part having an overall length short enough to secure subcutaneously injection and the cartridge part having an overall length long

enough to extend into the interior of the cartridge when said injection needle is fastened onto said syringe,

wherein:

said injection needle further is provided with a movable safety shield movable mounted relatively to said needle hub and which movable safety shield surrounds at least most of the injection part of said needle cannula when said needle cannula is in an unused state, and

b  
said safety shield can be longitudinal moved relatively to said needle cannula, such that said safety shield is first moved in the proximal direction when the injection part of the cannula is penetrated into the subcutis layer of a human body, thereby exposing the major part of the injection part to the human body, and automatically moved in the distal direction by a resilient element located between said needle hub and said safety shield when the injection part of said cannula is removed from the subcutis layer of the human body, and

said safety shield is irreversible locked in a locked safe position where the movable safety shield covers the skin piercing end of the injection part of said needle cannula when the injection part of said cannula is fully removed from the subcutis layer of a human body, and said double pointed disposable injection needle further is provided with means providing the user with a visual indication when said disposable double pointed injection needle is in the safe position.

13.  
30. A disposable double pointed injection needle according to claim 29,<sup>12</sup> wherein said needle hub is provided with at least one indicating area and said safety shield is provided with at least one transparent area through which transparent areas the indicating areas is visible when said safety shield has been moved to the irreversible locked position thereby providing the user with a visual indication when said disposable double pointed injection needle is in a potentially safe position.

31. 14.

A disposable double pointed injection needle according to claim <sup>13</sup>30, characterized in that, said hub further is provided with at least one additional indicating area which is visible through the transparent areas when said needle cannula is in the unused state.

32. 15.

A disposable double pointed injection needle according to claim <sup>13</sup>30, characterized in that, said safety shield is provided with at least one indicating area and that said needle hub is provided with at least one transparent area through which transparent areas the indicating areas is visible when said safety shield has been moved to the irreversible locked position thereby providing the user with a visual indication when said disposable double pointed injection needle is in a potentially safe position.

33. 16.

A disposable double pointed injection needle according to claim <sup>15</sup>32, characterized in that, said safety shield further is provided with at least one additional indicating area which is visible through the transparent areas when said needle cannula is in the unused state.

34. 17.

A disposable double pointed injection needle according to claim <sup>14</sup>31, characterized in that, the indicating areas and the additional indicating areas are provided with different colors, different symbols or different colors and different symbols.

### REMARKS

Claims 1-17 have been canceled without prejudice or disclaimer. Claims 18-34 have been added and therefore are pending in the present application. Claims 18-34 are supported by the specification, drawings, and originally filed claims.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

In the previous Office Action the Examiner rejected claims 1-7 under 35 U.S.C § 102(b) in view of U.S. Patent No. 6,162,197 and rejected claim 12 in view of U.S. Patent No. 5,674,204. In addition, the Examiner rejected claims 1-7 under 35 U.S.C. § 112 and objected to claims 8-11 and 13-17.